UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/562,205	05/15/2006	Ezio Bombardelli	2503-1186	5416

466 7590 10/05/2007

YOUNG & THOMPSON
745 SOUTH 23RD STREET
2ND FLOOR
ARLINGTON, VA 22202

EXAMINER	
CHEN, CATHERYNE	
ART UNIT	**PAPER NUMBER**
1655	

MAIL DATE	DELIVERY MODE
10/05/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/562,205	BOMBARDELLI, EZIO	
	Examiner	Art Unit	
	Catheryne Chen	1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 July 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-5,7 and 8* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5, 7-8* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The Amendments filed on July 13, 2007 has been received and entered. Currently, Claims 1-5, 7-8 are pending. Claims 1-5, 7-8 are examined on the merits. Claims 6 and 9 are canceled. The declaration of Ezio Bombardelli filed July 13, 2007 has been considered.

Election/Restrictions

Applicant's election without traverse of Group I (Claims 1-5, 7-8) in the reply filed on Jan 26, 2007 is acknowledged. The election of species is referred to Example 1 in the Specification, which are Salix rubra extract, Boswellia serrata extract, Green Tea extract, N-acetyl-glucosamine, Glucuronolactone, Enothera biennis oil.

Response to Arguments

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chrubasik et al. (Pain Digest, 1998, 8: 231-236), Tameja et al. (US 5629351), Charters et al. (US 6541045), Kemper (http://www.mcp.edu/herbal/default.htm), Lockhoff et al. (US 4710491) for the reasons set forth in the previous Office Action. All of Applicant's arguments regarding this ground of rejection have been fully considered but are not persuasive. Applicant argues that there is no sufficient suggestion to combine the ingredients.

In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by

combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988)and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, the ingredients are known inflammatory mediator. Chrubasik et al. teaches anti-inflammatory drugs of 360 mg, 11% of salicylic alcohol from Salix species (abstract, Clinical Studies). Tameja et al. teaches gum resin of Boswellia serrata has been used for the treatment of arthritis (column 1, lines 9-11).

Charters et al. teaches anti-inflammatory drug of about 1% to about 5%, about 10 to about 40 mg of N-acetyl D-glucosamine (abstract, column 8, lines 50-51, 63-63). Applicant argues that the compound is admixed differently then claimed.

In response to applicant's argument that the compound is admixed differently, the fact that applicant has recognized another advantage which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise be obvious. See *Ex parte Obiaya*, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985).

Kemper teaches proanthocyanidin in green tea is effective for treating inflammation (page 2). Applicant argues that the effect of proanthocyanidins are unclear.

A disclosure of the exact mechanism of action is not required. The reference specifically claims using proanthocyanidins in a composition to treat inflammation. The

reference gives the activity and the appropriate dosage amount to treat inflammation. Therefore, an artisan of ordinary skill would clearly see that this reference shows that using proanthocyanidins to treat inflammation was known in the art at the time of the invention.

Lockhoff et al. teaches anti-arthritic compound of 15 g of D-glucuronolactone (column 11, line 6). Applicant argues that there is no teaching of methylglucuronate.

In response to no methylglucuronate taught, the Applicant's claim is drawn to either glucuronic acid or glucuronolactate. As long as one of the ingredients is taught, then the claim is properly taught by the reference.

All the state diseases are inflammation related ailments, which are painful. Thus, it would be obvious to combine them to treat pain.

Claims 1-4,5, 7-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chrubasik et al. (Pain Digest, 1998, 8: 231-236), Tameja et al. (US 5629351), Charters et al. (US 6541045), Kemper (http://www.mcp.edu/herbal/default.htm), Lockhoff et al. (US 4710491) as applied to claims 1-4 above, and further in view of Chen et al. (US 2002/0032171 A1) and Belch et al. (The American Journal of Clinical Nutrition, 2000, 71: 352S-356s) for the reasons set forth in the previous Office Action. All of Applicant's arguments regarding this ground of rejection have been fully considered but are not persuasive. Applicant argues that there is no sufficient motivation to combine the formulation.

See discussion above. However, they do not teach Oenothera biennis oil.

Chen et al. teaches triglyceride of Oenothera biennis oil (evening primrose) to improve delivery of therapeutic agents (paragraphs 0002, 0036 Table 1). Therefore, in addition to its use to solubilize the ingredients and provide a carrier for absorption into the skin or consumption. For one to select a carrier over another are determined by many factors, such as cost, toxicity, and taste. Primrose oil is a good alternative as an carrier because it is natural and it has been used in the market to treat rheumatoid conditions. Thus it serves at least two functions to treat inflammatory disease.

Applicant claims that with all the ingredients combined, the ingredients are more effective. It has been known that drugs working at different levels of the inflammation pathway can increase efficacy in an additive manner. Tab. 1-3 show that with one drug, there is slight increase in the efficacy of the drugs; however, with all of the drugs combined (group 7), there is about 44% increase in efficacy. In group 7, the concentration of the drug used is 600 mg. Instead of 3 fold increase in the % variation compared to group 1's base line % variation, there is only about one fold increase. When one adds up the increases from groups 2 through 6, the % variation is only 37%, which is less than that of group 7's % variation. When standard deviations are considered, there really is no significant difference in the % variations. Therefore, the percentage change in group 7 shows additive rather than synergistic effects. As discussed in MPEP 716.02(a), a demonstration of additive results is not considered to be evidence of nonobviousness. Thus, the claim that all of the claimed ingredients can increase efficacy is not unforeseen or nonobvious. Furthermore, it must be pointed out that the Applicant's claim is toward the compound Bowellia serrata, while the compound

in group 3 is Boswellia "senolee." Thus, there is no true comparison for the efficacy effects.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Catheryne Chen whose telephone number is 571-272-9947. The examiner can normally be reached on Monday to Friday, 9-5 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on 571-272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Catheryne Chen
Patent Examiner
Art Unit 1655

/Susan Hoffman/
Primary Examiner, Art Unit 1655
September 26, 2007